FEB - 2 2001

K003710

Endoscopy Division
Smith & Nephew, Inc.
160 Dascomb Road, Andover, MA 01810 U.S.A.
Telephone: 978-749-1000
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Smith+Nephew

510(k) Summary
Dyonics Vision 337 Autoclavable Camera Head and Camera Coupler
Date Prepared: November 30, 2000

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter

Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, MA 01810

B. Company Contact

Janice Haselton
Regulatory Affairs Specialist

C. Device Name

Trade Name:	Dyonics Vision 337 Autoclavable Camera Head and Camera Coupler
Common Name:	Camera Head and Camera Coupler
Classification Name:	Endoscope and/or Accessories

D. Predicate Devices

Dyonics Digital 3-Chip Color Video Camera K972471
Dyonics DyoCam Video Camera K914919
Dyonics Camera Coupler K972471

E. Description of Device

The proposed Dyonics Vision 337 Autoclavable Camera Head and Camera Coupler can be used in conjunction with any direct-view endoscope or appropriate video-endoscope, control unit, light source, and monitor to allow illumination and visualization of articular cavities, body cavities, hollow cavities and canals. The camera head acts to transmits real time video images of the surgical site to the camera control unit. It then processes and displays the image to a viewing system or recording media.
The camera head attaches to the endoscope by means of a camera coupler.
The camera head and the camera coupler are hermetically sealed to allow for autoclavability.

F. Intended Use

The Dyonics Vision 337 Autoclavable Camera Head and Camera Coupler are indicated for use in endoscopic surgical procedures to provide illumination and allow visualization of articular cavities, body cavities, hollow organs and canals when used in conjunction with an appropriately indicated endoscope.

Additionally, the Dyonics Vision 337 Autoclavable Camera Head and Camera Coupler are indicated for use in endoscopic surgical procedures in the thoracic cavity when used in conjunction with an appropriately indicated thoracoscope.

G. Comparison of Technological Characteristics

The Dyonics Vision 337 Autoclavable Camera and Camera Coupler are substantially equivalent in design, materials of construction, and function and intended use as to the Smith & Nephew Images Digital 3-Chip Color Video Camera and Dyonics Camera Coupler.

Janice Haselton

Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 2001

Ms. Janice Haselton
Regulatory Affairs Specialist
Smith & Nephew
Endoscopy Division
160 Dascomb Road
Andover, Massachusetts 01810

Re: K003710
Trade Name: Dyonics Vision 337 Autoclavable Camera Head and Camera Coupler
Regulatory Class: II
Product Code: KOG, GCJ
Dated: November 30, 2000
Received: December 1, 2000

Dear Ms. Haselton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K003710

Device Name : Dyonics Vision 337 Autoclavable Camera Head and Camera Coupler

Indications for Use :

The Dyonics Vision 337 Autoclavable Camera Head and Camera Coupler are indicated for use in endoscopic surgical procedures to provide illumination and allow visualization of articular cavities, body cavities, hollow organs and canals when used in conjunction with an appropriately indicated endoscope.

Additionally, the Dyonics Vision 337 Autoclavable Camera Head and Camera Coupler are indicated for use in endoscopic surgical procedures in the thoracic cavitity when used in conjunction with an appropriately indicated thoracoscope.

(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003710

Prescription Use ✓ OR Over-the-Counter ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)